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June 9, 2003

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Company: USPTO	Your Ref.: 09/781,301

Confirmation copy will not follow.

Re: Resubmission of Response to Notice of Improper
Request for Continued Examination

Message

Please process the attached documents which were originally filed on May 23, 2002 relating to the above-identified patent application.

If you have any problems regarding this transmission, please contact Paul E. Dietze, Ph.D. at (202) 490-4460.

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COPY

Express Mail No. _____
 Date Mailed 05-23-02 First Class Mail ()
 Serial No. 09/781,301
 Inventor DI PIERRO Filed 02-13-01
For Cosmetic Compositions Having Retarding Action on the
Regrowth of Superfluous Hair

- | | |
|---|--|
| <input type="checkbox"/> Affidavit/Declaration | <input type="checkbox"/> Fee Address Indication Form |
| <input type="checkbox"/> Amendment () Response | <input type="checkbox"/> Fee Calculation |
| <input type="checkbox"/> Application _____ pages | <input type="checkbox"/> Issue Fee Transmittal |
| <input type="checkbox"/> _____ claims _____ drawing sheets | <input type="checkbox"/> Notice of Appeal |
| <input type="checkbox"/> Assignment () Cover Sheet | <input type="checkbox"/> Oral Hearing Request/Confirm |
| <input type="checkbox"/> Brief (in triplicate) | <input type="checkbox"/> Petition to Extend Time _____ month(s) |
| <input type="checkbox"/> Declaration & Power of Attorney | <input type="checkbox"/> Petition under 37 C.F.R. _____ |
| <input type="checkbox"/> Executed () Unexecuted () Copy | <input type="checkbox"/> Power of Attorney |
| <input type="checkbox"/> Declaration of Inventor(s) | <input type="checkbox"/> () by Assignee () Associate () with Revocation |
| <input type="checkbox"/> Executed () Unexecuted () Copy | <input type="checkbox"/> Request for Correction of Filing Receipt |
| <input type="checkbox"/> Design Application | <input type="checkbox"/> Sequence Listing w/Computer Readable and Paper Copy |
| <input type="checkbox"/> Disclaimer () Disclaimer Fee | <input type="checkbox"/> Small Entity Statement |
| <input type="checkbox"/> Disclosure Statement () Form PTO-1449 | <input type="checkbox"/> Status Letter |
| <input type="checkbox"/> () w/refs. () w/o refs. | <input type="checkbox"/> Transmittal Letter |
| <input type="checkbox"/> Drawings, Formal | |
| _____ Sheets _____ Figures | |



Other: Response to Notice of Improper Request for Continued Exam.
Request for Refund of Petition to Revoke Request for Refund
 File No. 4914-073 Sender: TO R/Per

COPY**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of: DI PIERRO

Appl. No.: 09/781,301

Art Unit: 1651

Filed: February 13, 2001

Examiner: FLOOD, M.

For: COSMETIC COMPOSITIONS HAVING
RETARDING ACTION OF THE
REGROWTH OF SUPERFLUOUS HAIR

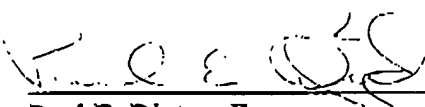
Attorney Docket No: 7914-090

REQUEST FOR REFUND UNDER 37 CFR § 1.28(a)Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The Request, filed April 8, 2002, to convert the Request for Continued Examination ("RCE"), filed March 18, 2002, to a Continuation Application was denied by USPTO on April 29, 2002. Accordingly, Applicants request a refund in the amount of \$740.00.

Respectfully submitted,

Date May 23, 2002

For: Paul E. Dietze, Esq. Reg. No. 45,627
Thomas G. Rowan Reg. No. 34,419**PENNIE & EDMONDS**
1667 K Street, N.W., Suite 1000
Washington, D.C. 20006-1605

(202) 496-4400

Enclosure

COPY #15**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: DI PIERRO

Application No.: 09/781,301

Group Art Unit: 1651

Filed: February 13, 2001

Examiner: M. Flood

For: COSMETIC COMPOSITIONS HAVING
RETARDING ACTION ON THE
REGROWTH OF SUPERFLUOUS HAIR

Attorney Docket No.: 7914-073-999

**PETITION TO REVIVE APPLICATION UNDER 37 C.F.R. § 1.137(b)
DUE TO UNINTENTIONAL ABANDONMENT****Box DAC****Attn: Office of Petitions**

Assistant Commissioner for Patents

Washington, D.C. 20231

Sir:

Applicant hereby petitions for revival of the above-identified application, which became unintentionally abandoned on March 18, 2002, due to a mistakenly filed Request for Continued Examination filed in response to a pending Office Action dated September 18, 2001.

The entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 C.F.R. § 1.137(b) was unintentional.

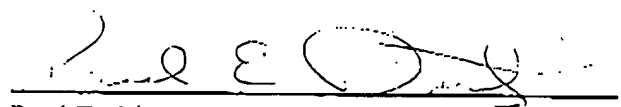
On March 18, 2002, which was also six months after the Office Action was issued by the United States Patent and Trademark Office ("USPTO"), a Request for Continued Examination ("RCE") was filed, along with provision for the required fees. Rather than filing a RCE, a Continuation application or a Continuation-in-Part application should have been filed, as prosecution on the merits was not closed according to 37 C.F.R. § 1.114(b). As stated in the Response to Notice of Improper Request for Continued Examination (copy attached), Applicant intended to keep the above-captioned application pending, as evidenced by the filing of an RCE and Applicant's attempts to timely perfect their submissions, once it was discovered that the RCE was mistakenly filed.

Applicant now petitions to revive this unintentionally abandoned application under 37 C.F.R. § 1.137(b) and respectfully request that the petition be granted. Enclosed are copies of a Response to Notice of Improper Request for Continued Examination, a Rule 1.53b Continuation-in-Part Application Transmittal, a Declaration, an information disclosure statement, and a proper Continuation-in-Part application, citing priority to the above-captioned application. See M.P.E.P. § 711.03(c)(III)(A) (which states, "[i]n a non-provisional application abandoned for failure to prosecute, the required reply may be met by the filing of a continuing application."). It is requested that these submissions be accepted pursuant to this petition.

Please charge the required fee for this petition, estimated to be \$1280.00, to Pennie & Edmonds LLP Deposit Account No. 16-1150. A copy of this sheet is enclosed.

Respectfully submitted,

Date: May 23, 2002


Paul E. Dietze
For: Thomas G. Rowan

(Reg. No. 45,627)
(Reg. No. 34,419)

PENNIE & EDMONDS LLP
1667 K Street, N.W.
Washington, DC 20006

(202) 496-4400

Attachments

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

COPY

Application of:

DI PIERRO

Application No.: 09/781,301

Group Art Unit: 1651

Filed: February 13, 2001

Examiner: M. Flood

For: COSMETIC COMPOSITIONS
HAVING RETARDING ACTION OF
THE REGROWTH OF
SUPERFLUOUS HAIR

Attorney Docket No.: 7914-073

**RESPONSE TO NOTICE OF IMPROPER
REQUEST FOR CONTINUED EXAMINATION (RCE)**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Notice of Improper Request for Continued Examination (RCE), mailed March 29, 2002, a copy of which is attached hereto, Applicants respectfully request that the Request for Continued Examination ("RCE") filed on March 18, 2002 be treated as a continuation application.

On March 18, 2002, Applicants filed a Petition for Extension of Time with provision for the appropriate fee and a RCE transmittal also with provision for the appropriate fee. The RCE, however, was filed when prosecution of the above-identified application was not closed. Accordingly, Applicants should have filed a continuation application. Applicants, by virtue of filing the RCE, obviously intended to keep the above-identified application pending. Therefore, Applicants respectfully request that the RCE filed in the above-identified matter on March 18, 2002 be treated as a continuation application. In accordance with instructions from Examiner Rene Pettus, in a telephone discussion on April 4, 2002, Applicants are filing herewith a Continuation Transmittal, with a copy of the application and declaration, a preliminary amendment, and an IDS to perfect the filing of the continuation application.

Applicants also enclose herewith a Request for Refund Under 37 C.F.R. § 1.128(a) to refund the filing fee for the RCE filed on March 18, 2002.

No fee is believed to be due for this submission. Should any fee be required, please charge such fee to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

Date April 8, 2002



45,627

Paul E. Dietze

(Reg. No.)

For: Thomas G Rowan

(Reg. No. 34,419)

PENNIE & EDMONDS LLP
1667 K Street, N.W., Suite 1000
Washington, D.C. 20006
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

COPY

Application of:

DI PIERRO

Appl. No.: 09/781,301

Art Unit: 1651

Filed: February 13, 2001

Examiner: FLOOD, M.

For: COSMETIC COMPOSITIONS HAVING
RETARDING ACTION OF THE
REGROWTH OF SUPERFLUOUS HAIR

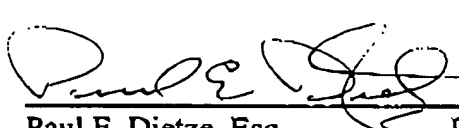
Attorney Docket No: 7914-073

REQUEST FOR REFUND UNDER 37 CFR § 1.28(a)Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

On March 18, 2002, Applicants filed a Request for Continued Examination ("RCE") with provision for the appropriate fee. The RCE, however, was filed when prosecution of the above-identified application was not closed and the RCE was deemed to be improper. Accordingly, Applicants request a refund in the amount of \$740.00.

Respectfully submitted,

Date April 3, 2002
For: Paul E. Dietze, Esq.
Thomas G. RowanReg. No. 45,627
Reg. No. 34,419**PENNIE & EDMONDS**
1667 K Street, N.W., Suite 1000
Washington, D.C. 20006-1605

(202) 496-4400

Enclosure

Please type a plus (+) inside this box -

COPY

PTO/SB/29 (12/95)

Approved for use through 09/30/00. OMB 0651-00

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UTILITY PATENT APPLICATION TRANSMITTAL <i>(Only for new nonprovisional applications under 37 CFR 1.53(b))</i>	Attorney Docket No.	7914-092	Total Pages	17
	First Named Inventor or Application Identifier			
	F. DI PIERRO			
	Express Mail Label No.	N/A		

APPLICATION ELEMENTS See MPEP chapter 600 concerning utility patent application contents.	ADDRESS TO: Assistant Commissioner for Patents Box Patent Application Washington, DC 20231
1. <input checked="" type="checkbox"/> Fee Transmittal Form <i>Submit an original, and a duplicate for fee processing</i> 2. <input checked="" type="checkbox"/> Specification [Total Pages <u>15</u>] <i>(preferred arrangement set forth below)</i> -Descriptive title of the invention -Cross Reference to Related Applications -Statement Regarding Fed sponsored R&D -Reference to Microfiche Appendix -Background of the invention -Brief Summary of the invention -Brief Description of the Drawings (if filed) -Detailed Description of the invention (including drawings, if filed) -Claim(s) -Abstract of the Disclosure 3. <input type="checkbox"/> Drawing(s) (35 USC 113) [Total Sheets <u> </u>] 4. <input checked="" type="checkbox"/> Oath or Declaration (Unexecuted) [Total Sheets <u>2</u>] a. <input type="checkbox"/> Newly executed (original or copy) b. <input type="checkbox"/> Copy from a prior application (37 CFR 1.63(d)) <i>(for continuation/divisional with Box 17 completed)</i> [Note Box 5 below] i. <input type="checkbox"/> DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33 (b). 5. <input checked="" type="checkbox"/> Incorporation By Reference (useable if Box 4b is checked) The entire disclosure of the prior application is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.	6. <input type="checkbox"/> Microfiche Computer Program (Appendix) 7. <input type="checkbox"/> Nucleotide and/or Amino Acid Sequence Submission <i>(if applicable, all necessary)</i> a. <input type="checkbox"/> Computer Readable Copy b. <input type="checkbox"/> Paper Copy (identical to computer copy) c. <input type="checkbox"/> Statement verifying identity of above copies
ACCOMPANYING APPLICATION PARTS	
8. <input type="checkbox"/> Assignment Papers (cover sheet & document(s)) 9. <input type="checkbox"/> 37 CFR 3.73(b) Statement <input type="checkbox"/> Power of Attorney <i>(when there is an assignee)</i> 10. <input type="checkbox"/> English Translation Document (if applicable) 11. <input checked="" type="checkbox"/> Information Disclosure <input type="checkbox"/> Copies of IDS Statement (IDS)/PTO-1449 Citations 12. <input type="checkbox"/> Preliminary Amendment 13. <input checked="" type="checkbox"/> Return Receipt Postcard (MPEP 503) <i>(Should be specifically itemized)</i> 14. <input type="checkbox"/> Applicant claims Small Entity status, see 37 C.F.R. § 1.27 15. <input type="checkbox"/> Certified Copy of Priority Document(s) <i>(if foreign priority is claimed)</i> 16. <input type="checkbox"/> Other:	

17. If a **CONTINUING APPLICATION**, check appropriate box and supply the requisite information:
☐ Continuation ☐ Divisional ☒ Continuation-in-part (CIP) of prior application No: 09/781,301 filed February 13, 2001.

18. CORRESPONDENCE ADDRESS

Customer Number: 20582	 (Insert Customer No. or Attach bar code label here)	or <input type="checkbox"/> Correspondence address below
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NAME					
ADDRESS					
CITY	STATE	ZIP CODE			
COUNTRY	TELEPHONE	FAX			

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231.

PENNIE & EDMONDS LLP
COUNSELLORS AT LAW
 1667 K Street, N.W.
 Washington, D.C. 20006
 (202) 496-4400

COPY

ATTORNEY DOCKET NO. 7914-092

Date: May 23, 2002

Assistant Commissioner for Patents
 Box PATENT APPLICATION
 Washington, D.C. 20231

Sir:

The following utility patent application is enclosed for filing:

Applicant(s): Francesco DI PIERRO

Executed on: Unexecuted

Title of Invention: COSMETIC COMPOSITIONS HAVING RETARDING ACTION ON THE REGROWTH OF
 SUPERFLUOUS HAIR

PATENT APPLICATION FEE VALUE

TYPE	NO. FILED	LESS	EXTRA	EXTRA RATE	FEE
Total Claims	22	-20	2	\$18.00 each	\$ 36.00
Independent	1	-3	0	\$84.00 each	\$ 0.00
Minimum Fee					\$ 740.00
Multiple Dependency Fee If Applicable (\$270.00)					\$ 0.00
Total					\$ 776.00
50% Reduction for Independent Inventor, Nonprofit Organization or Small Business Concern (a verified statement as to the applicant's status is attached)					\$ 0.00
Total Filing Fee					\$ 776.00

- ☐ DO NOT PUBLISH. I hereby certify that the invention disclosed in the attached application has not and will not be the subject of an application filed in another country, or under a multilateral agreement, that requires publication at eighteen months after filing. I hereby request that the attached application not be published under 35 U.S.C. 122(b).
- ☒ Priority of application no. MI2000A000628 filed on March 24, 2000 in Italy is claimed under 35 U.S.C. § 119.
- ☒ The certified copy of the priority application has been filed in application no. 09/781,301 filed February 13, 2001.
- ☐ Amend the specification by inserting before the first line the following sentence: This is a continuation-in-part of application no. filed .

Please charge the required fee to Pennie & Edmonds LLP Deposit Account No. 16-1150. A copy of this sheet is enclosed.

Respectfully submitted,



Paul E. Dietze
 For: Thomas G. Rowan
 PENNIE & EDMONDS LLP

(Reg. No. 45,627)
 (Reg. No. 34,419)

COPY

COSMETIC COMPOSITIONS HAVING RETARDING ACTION ON THE REGROWTH OF SUPERFLUOUS HAIR

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of Application No. 09/781,301, filed February 13, 2001, the contents of which are expressly incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to cosmetic compositions having retarding action on the regrowth of superfluous hair, more particularly to cosmetic compositions containing lipophilic extracts of *Serenoa* (*Serenoa repens*) enriched in fatty acids and with a reduced content of sterols.

BACKGROUND OF THE INVENTION

In humans, the main characteristics concerning the development of hair (number, color, thickness, length, and distribution) involve the consequence of an action mediated by sexual hormones, which in turn, are derived from genetic expression.

In Western Countries, as well as in other socioeconomically advanced Countries, hair of limbs and armpits, pubic hair which can come out of bathing suits, as well as hair which can, although rarely, grow around the mammary areola, is considered unaesthetic in women. The term "superfluous hair" indicates indeed the growth of hair in these areas. As such superfluous hair is of course unwanted, it can be subjected to epilation (removal of the whole hair, roots included, by means of wax or electrolysis) or depilation (removal of the hair starting from the surface of the skin by chemical destruction of keratin, blade or electric shaving, or repeated traumatism of hair). All of these procedures are, however, at least partly traumatic to the skin. These procedures may induce both inflammation in the tissues directly underlying the treated skin and lesions in capillaries and peripheral small vessels. There is therefore the need for such consequences to be reduced as well as for the regrowth of superfluous hair to be retarded as much as possible.

Soler at al. (US6113926) disclose cosmetic formulations containing glycolic or glyceric extracts of *Serenoa* rich in antiandrogenic sterols, which can be used for the treatment of hirsutism or for controlling and retarding hair loss.

Barr, E. (WO98/33472) discloses pharmaceutical or cosmetic compositions for the prevention or treatment of hirsutism comprising, as an active ingredient, a lipophilic extract of fruits of *Serenoa repens* plants, which contains a mixture of fatty acids, long-chained alcohols, sterols and triterpenic alcohols, and the esters thereof.

FR2791255 discloses cosmetic compositions containing vegetal complexes from plants such as *Serenoa repens*, obtained by means of conventional techniques including extraction with solvents or hypercritical CO₂. The reduction of hair growth is attributed to phytosterols that show 5 α -reductase inhibition.

SUMMARY OF THE INVENTION

One aspect of the present invention relates to a superfluous-hair-growth-retarding cosmetic composition comprising as active ingredient a lipophilic extract enriched in fatty acids and with a reduced sterol content.

Advantageously, the active ingredient(s) are present in a therapeutically or cosmetically effective amount sufficient to provide a retarding action on the growth of superfluous hair. In one preferred embodiment, the amount of the active ingredient(s) present are from 0.1% to about 3% by weight.

The composition may further include anti-inflammatory and/or vasal protective- and/or anti-itching agents, e.g., such as triterpenes from liquorice; saponins from a horse chestnut plant; triterpenes from *Terminalia sericea*; isobutylamides from *Zanthoxylum bungeanum*; ginkgoflavoneglucosides and terpenes from *Ginkgo*; polyphenols from grapes seeds; anthocyanosides from bilberries; saponins from butcher's broom; or a mixture thereof. In one embodiment, each anti-inflammatory or vasal protective agent is present in an amount from about 0.1% to about 3% by weight.

The composition may also further include a pharmaceutically or cosmetically acceptable carrier, excipient, or adjunct, preferably including a phospholipid, which can form a complex with the active ingredients, thereby improving absorption or effectiveness.

Advantageously, the composition is in the form of a liquid, a solid, or a semi-solid, *e.g.*, such as a lotion, a milk, a solution, an emulsion, a cream, a paste, a gel, a foam, or a combination thereof.

The composition may also further include one or more conventional depilatory agents, *e.g.*, such as a thiol derivative; thioglycolic or thiolactic acid, or an alkali or alkaline-earth metal salt thereof; ethanolamine thioglycate; aminoethanethiol; mercaptopropionic acid; thiglycic or thioacetic acid; barium sulfate; or a mixture thereof.

The composition may also further include a conventional depilation accelerator, preferably based on a compound containing a urea, a thiourea, or a biguanide, or a combination of such compounds.

Another aspect of the invention relates to a cosmetic treatment method, which includes applying to a region of the body having superfluous hair a cosmetically or therapeutically effective amount of any of the compositions detailed above.

Advantageously, the therapeutically or cosmetically effective amount is sufficient to provide a retarding action on the growth of superfluous hair. In addition, these methods can involve applying from about 0.01 mL to about 0.1 mL of the composition per square centimeter of skin area.

DETAILED DESCRIPTION OF THE INVENTION

The lipophilic extracts of *Serenoa* enriched in fatty acids and with a reduced content of sterols according to the invention are prepared as disclosed in EP 250953, which is herein entirely incorporated by reference.

The extractive process is carried out at temperatures ranging from 30° to 50°C, pressures ranging from 100 to 350 bars, and the evaporation at temperatures ranging from 20° to 30°C, at pressures ranging from 50 to 70 bars. The extracts obtained in these conditions contain at least 85% of fatty acids (free or esterified), whereas the content in phytosterols is lower than 0.4% (w/w). The extraction of *S. repens* fruits with hypercritical CO₂ gives directly an oil that can be used without further purification.

Notwithstanding the extremely low content of phytosterols, the oily extract obtained from the process indicated above showed, during biochemical and pharmacological tests, a significant anti-androgenic, hormone-regulating action.

Object of the present invention is therefore to provide cosmetic composition having retarding action on the regrowth of superfluous hair and containing a lipophilic extract of *Serenoa repens* with a content of fatty acids higher than 85% (by weight) and a content of sterols lower than 0.4%.

Another aspect of the present invention relates to cosmetic compositions further containing anti-inflammatory and/or vasal protective and/or anti-itching agents, preferably including at least one of: anti-inflammatory triterpenes from liquorice (*Glycyrrhiza glabra*); anti-edematous and anti-inflammatory saponins from horse chestnut (*Aesculus hyppocastanum*); triterpenes from *Terminalia sericea*; analgesic and anti-inflammatory isobutylamides from *Zanthoxylum bungeanum* (sin Alatum); vasal protective ginkgo flavone glucosides and terpenes from ginkgo (*Ginkgo biloba*); vasal protective polyphenols from grapes seeds (*Vitis vinifera*); vasal protective anthocyanosides from bilberries (*Vaccinium myrtillus*); and vasal protective saponins from butcher's broom (*Rescus aculeatus*). These preferred compositions of the invention can contain either the above indicated pure components or extracts containing them, preferably in an amount from about 0.1% to about 3% by weight.

In a preferred embodiment, the derivatives listed above are complexed with phospholipids.

The additional ingredients, their phospholipidic complexes and the processes for the preparation thereof, may be found in, *inter alia*, U.S. Patent No. 5,547,673; International Publication No. WO 00/02570; and European Patent Nos. EP 0,283,713 and EP 0,275,224, the disclosures of all of which are incorporated herein by express reference hereto.

These derivatives can provide anti-inflammatory, analgesic, vasal tonifying, anti-edematous, and/or tonifying activity, which make them useful in the treatment of inflammatory conditions and vasculopathies, and in dealing with capillary fragility.

"Retarding action" as used herein pertaining to hair regrowth, means an action which induces a delay in hair growth rate, a decrease in the amount of growing hair, or both.

According to the present invention, the cosmetic compositions can be in the form of post-depilatory or post-epilatory compositions, *i.e.* to be used subsequently depilation or epilation, or they may be included in depilatory formulations.

"Depilatory formulations", as used herein, means formulations capable of removing hair by the cleavage of keratin disulfide bonds, thereby destroying hair or weakening it to the extent that it can easily be removed (*e.g.*, mechanically by means of a spatula, a sponge or simply by washing with water). Conventional depilatory formulations can further contain as an active ingredient thiol derivatives, such as thioglycolic and thiolactic acids, or an alkali and alkaline-earth metal salts thereof; ethanolamine thioglycate; aminoethanethiol; mercaptopropionic acid; thioglycic and thioacetic acids; barium sulfate; or a mixture thereof.

"Post-depilatory compositions", as used herein without reference to post-epilatory compositions, should be understood to refer to both post-depilatory and post-epilatory compositions, for the sake of simplicity.

For the preparation of the cosmetic/pharmaceutical compositions of the invention, the active ingredients indicated above are mixed with pharmaceutically/cosmetically acceptable carriers or excipients.

The compositions will be suitably formulated as a liquid, *e.g.*, such as a lotion, a milk, a solution, an emulsion, or the like, or a combination thereof, or as a solid or semi-solid, *e.g.*, such as a cream, a paste, a gel, a foam, or the like, or a combination thereof. For this purpose, the compositions of the invention may also contain pharmaceutically and/or cosmetically acceptable carriers, excipients, or adjuncts conventionally used for the preparation of formulations. These formulation may include those for topical use, thus including, for example, viscosity agents, such as tragacanth, xanthan gum, gypsum, clay, magnesium oxide, talc, or a combination thereof; chelating agents, such as ethylenediaminetetracetic acid or disodium edetate; emollients, such as cetyl and stearyl alcohols, liquid paraffin, glyceryl stearate, silicon oils, hydrocarbon oils and waxes; wetting agents, such as urea or 1,3-butylene glycol; emulsifiers, such as medium chain triglycerids, acrylic acid polymers, ethoxylated stearyl or cetyl alcohols, polyoxyethylene alkyl ethers, or a mixture thereof; absorption promoters, such as cyclodextrans and liposomes; antioxidants, such as

ascorbyl palmitate, tocopherol; preservatives, such as glycerin, propylene glycol; stabilizing agents; or fragrances; or a mixture thereof.

Other compositions according to the invention, such as depilatory compositions, may further contain other conventional additives, for example, depilation accelerators, such as those based on ureas, thioureas and biguanides.

Another aspect of the present invention further relates to a method of cosmetic treatment in order to retard the growth of superfluous hair. The method includes applying a cosmetically effective amount of the compositions of the invention on the body area where unwanted hair grows. The amount of the composition to be applied and the frequency of application will vary depending on the area to treat and on the personal characteristics of the user. Generally, it can range from about 0.01 mL to about 0.1 mL of composition per cm² of skin area, typically to be applied 1 to about 3 times a day during initial treatment, subsequently reducing the frequency, *e.g.*, to approximately one application on alternate days, depending on the results obtained or desired.

Tests were carried out on healthy female volunteers, of age ranging from about 22 to about 40 years, using: a) post-depilatory compositions according to the invention, for use after superfluous hair had been removed with conventional methods; b) conventional depilatory compositions, containing the compositions of the invention; c) conventional depilatory compositions, containing no compositions of the invention.

In the case of treatments with a) and b), hair regrowth was complete not before 3 weeks, progressively decreasing with the progress of treatment; furthermore, regrown hair appeared weakened. Conversely, in treatment with c), hair regrowth was complete within about 2 to about 3 weeks.

EXAMPLE

The following examples are only representative of the methods and materials for use cosmetic compositions according to the invention, and are not to be construed as limiting the scope of the invention in any way.

Example 1:

In a 5 L extractor, equipped with heating and with all the accessories for pressure control, 1.2 kg of *Serenoa repens* fruits, finely ground by a cryocontusion process (cold grinding at -20°C), were extracted.

The drug was extracted, using subsequently 10 L of continuous recycling CO_2 , for 2 hours, at a temperature of 35° and 250 bars. After evaporation of the solvent, the extracted material was recovered and dried at 2 mmHg and 45°C for 24 hours.

In this way, 0.138 kg of a yellow orange clear oil, with the following characteristics, were obtained:

Thickness: 0.896

Refraction index: 1.46

Substances that cannot be saponified: 2.52%

Saponification index: 230

Content in free fatty acids: 86%.

Example 2:

In a 5 L extractor, equipped with heating and with all the accessories for pressurization and its controls, 1.2 kg of *Serenoa Repens* fruits finally ground by cryogrinding were extracted as in Example 1.

The drug was on the whole extracted with 10 L of continuous recycling CO_2 for 2 hours at a temperature of 45°C and 220 bars, keeping a temperature of 25°C and 50 bars in the condenser.

When the extraction was complete, after a complete evaporation of CO_2 from the condenser, the extracted oil saturated with water was recovered and filtered on 12 g of anhydrous sodium sulphate.

145 g of yellow orange oil were obtained; the oil was dried under vacuum at 2 mm/Hg at 50° for a complete dehydration, and it has the same characteristics as the oil obtained in Example 1.

Example 3: Post-Depilatory Gel Formulation

A formulation according to the invention was prepared containing 2% lipophilic extract of *serenoa repens*, 0.3% ruscogenins, and 0.5% *zanthoxylum bungeanum* extract.

100 g contain:

<i>Serenoa repens</i> * lipophilic extract	2 g
Ruscogenins	0.3 g
20% <i>zanthoxylum bungeanum</i> ** extract solution (in water)	0.5 g
Ethanol	20 g
PEG-6-Caprylic /Capric Glycerides (SOFTIGEN 767, from Huls)	15 g
Propylene glycol	10 g
Oleth 20 (VOLPO 20, from Croda)	5 g
Dimethicone copolyol	2.5 g
Carbomer	2 g
Triethanolamine	1 g
Zinc ricinoleate (TEGODOR HY77, from Teco)	0.2 g
Menthol	0.5 g
Preservatives	0.5 g
Antioxidants	q.s.
Purified water	q.s. to 100 g

* Prepared according to US 5,547,673.

** Prepared according to International Publication No. WO 00/02570.

Example 4: Post-Depilatory Oil-in-Water Emulsion Formulation

A formulation according to the invention was prepared containing 1% glycyrrhetic acid complex with phospholipids, 2% *serenoa repens*, and 1% ruscogenins.

100 g contain:

<i>Glycyrrhetic acid complex with phospholipids</i> *	1 g
Ruscogenins**	1 g
<i>Serenoa repens</i> lipophilic extract	2 g
Glyceryl stearate (CUTINA GMS, from Henkel)	7 g

Polysorbate 60 (TWEEN 60, from ICI)	5 g
Propylene glycol	5 g
Octyldodecanol (EUTANOL G, from Henkel)	4 g
Wheat germ oil	3 g
PEG-S soy sterols (GENEROL 122 ES, from Henkel)	2 g
Dimethicone	1 g
Carbomer	0.6 g
Tocopherol	0.2 g
Ascorbyl Palmitate	0.1 g
10% sol. NaOH solution (in water)	2 g
Disodium EDTA	0.1 g
Zinc ricinoleate (TEGODOR CW90, from Tego)	0.2 g
Preservatives	q.s.
Fragrance	q.s.
Purified water	q.s. to 100 g

* Prepared according to European Patent No. EP 0283713.

** Prepared according to European Patent No. EP 0250953.

Example 5: Post-Depilatory Oil-in-Water Emulsion Formulation

A formulation according to the invention was prepared containing 1.5% glycyrrhetic acid complex with phospholipids, 0.5% *Vitis vinifera* procyanidolic oligomers complex with phospholipids, and 2% *Serenoa repens* lipophilic extract.

100 g contain:

<i>Glycyrrhetic acid complex with phospholipids*</i>	1.5 g
<i>Vitis vinifera</i> procyanidolic oligomers complex with phospholipids **	0.5 g
<i>Serenoa repens</i> lipophilic extract	2 g
Propylene glycol	5 g
Modified jojoba oil (CETIOL J600, from Henkel)	5 g
Cetyl Alcohol	5 g

Glyceryl stearate (Cutina GMS - Henkel)	5 g
Polysorbate 60 (Tween 60 - ICI)	3 g
Hectorite (and) hydroxyethylcellulose (Betone LT - Rheox)	0.5 g
Dimethicone 350	0.5 g
Zinc Ricinoleate (TEGODOR CW90, from Tego)	0.2 g
Disodium edetate	0.1 g
Tocopherol	0.2 g
Ascorbyl palmitate	0.1 g
Sodium Metabisulfite	0.1 g
Citric acid	0.1 g
Preservatives	q.s.
Fragrance	q.s.
Purified water q.s. to 100 g	

* Prepared according to European Patent No. EP0283713.

** Prepared according to European Patent No. EP0275224.

Example 6: Post-Depilatory Alcoholic Lotion Formulation

A formulation according to the invention was prepared containing 0.1% 18/ β -glycyrrhetinic acid, 1% *Ginkgo biloba*, and 0.5% *Serenoa repens*.

100 mL contains:

18/ β -glycyrrhetinic acid	0.1 g
<i>Ginkgo biloba</i> dry extract (containing 20% saponins)	1 g
<i>Serenoa repens</i> purified extract	0.5 g
Cyclomethicone	10 g
PEG-40 Hydrogenated castor oil (CREMOPHOR RH40, from BASF)	1 g
Zinc Ricinoleate (TEGODOR HY77, from Tego)	0.2 g
Butylated Hydroxytoluene	0.05 g
Fragrance	q.s.
Alcohol	q.s. to 100 mL

Example 7: Post-Depilatory Gel Formulation

A formulation according to the invention was prepared having 2% *Serenoa repens* lipophilic extract.

100 g contain:

<i>Serenoa repens</i> lipophilic extract	2 g
Ethanol	20 g
PEG-6-Caprylic/Capric Glycerides (SOFTIGEN 767, from Huls)	15 g
Propylene glycol	10 g
Oleth 20 (VOLPO 20, from Croda)	5 g
Dimethicone copolyol	2.5 g
Carbomer	2 g
Triethanolamine	1 g
Zinc ricinoleate (TEGODOR HY77, from Teco)	0.2 g
Menthol	0.5 g
Preservatives	q.s.
Antioxidants	q.s.
Purified water q.s. to 100 g	

It is to be understood that the invention is not to be limited to the exact configuration as illustrated and described herein. For example, it should be apparent that a variety of materials would be suitable for use in the cosmetic compositions or cosmetic treatment method according to the Detailed Description of the Preferred Embodiments. Accordingly, all expedient modifications readily attainable by one of ordinary skill in the art from disclosure set forth herein, or by routine experimentation therefrom, are deemed to be within the spirit and scope of the invention as defined by the appended claims.

CLAIMS

What is claimed is:

1. A cosmetic composition comprising a lipophilic extract of *Serenoa repens* in an amount sufficient to provide a retarding action on the growth of superfluous hair, wherein said lipophilic extract has a fatty acids content of at least about 85% (w/w) and a phytosterols content of less than about 0.4%.
2. The composition of claim 1, further comprising an anti-inflammatory, vasal protective agent, or anti-itching agent.
3. The composition of claim 2, wherein the anti-inflammatory agent is selected from the group consisting of triterpenes from liquorice (*Glycyrrhiza glabra*), saponins from horse chestnut plant (*Aesculus hyppocastanum*), triterpenes from *Terminalia sericea*, isobutylamides from *Zanthoxylum bungeanum* (sin Alatum) and mixtures thereof and the vasal protective agent is selected from the group consisting of ginkgo flavone glucosides and terpenes from Ginkgo (*Ginkgo Biloba*), polyphenols from grapes seeds (*Vitis vinifera*), anthocyanosides from bilberries (*Vaccinium myrtillus*), saponins from butcher's broom (*Rescus aculeatus*), and mixtures thereof.
4. The compositions of claim 3, wherein each anti-inflammatory agent, vasal protective agent, or anti-itching agent is present in an amount from about 0.1% to about 3% by weight.
5. The composition of claim 2, wherein each anti-inflammatory agent, vasal protective agent, or anti-itching agent is complexed with one or more phospholipids.
6. The composition of claim 1, further comprising a pharmaceutically or cosmetically acceptable carrier or excipient.

7. The composition of claim 2, further comprising a pharmaceutically or cosmetically acceptable carrier or excipient.
8. The composition of claim 1, wherein the lipophilic extract of *Serenoa repens* is present in an amount of about 0.1% to about 3% by weight.
9. The composition of claim 1, in the form of a liquid, a solid, or a semi-solid.
10. The composition of claim 9, in the form of a lotion, a milk, a solution, an emulsion, a cream, a paste, a gel, a foam, or a combination thereof.
11. The composition of claim 2, in the form of a liquid, a solid, or a semi-solid.
12. The composition of claim 11, in the form of a lotion, a milk, a solution, an emulsion, a cream, a paste, a gel, a foam, or a combination thereof.
13. The composition of claim 1, further comprising a conventional depilatory agents.
14. The composition of claim 2, further comprising a conventional depilatory agents.
15. The composition of claim 1, wherein the conventional depilatory agents comprises a thiol derivative; thioglycolic acid, thiolactic acid, or an alkali or alkaline-earth metal salt thereof; ethanolamine thioglycate; aminoethanethiol; mercaptopropionic acid; thioglycic acid, thioacetic acid; barium sulfate; or a mixture thereof.
16. The composition of claim 2, wherein the conventional depilatory agents comprises a thiol derivative; thioglycolic acid, thiolactic acid, or an alkali or alkaline-earth metal salt thereof; ethanolamine thioglycate; aminoethanethiol; mercaptopropionic acid; thioglycic acid, thioacetic acid; barium sulfate; or a mixture thereof.

17. The composition of claim 1, further comprising a conventional depilation accelerator.
18. The composition of claim 17, wherein the conventional depilation accelerator comprises a urea, a thiourea, a biguanide, or a combination thereof.
19. The composition of claim 2, further comprising a conventional depilation accelerator.
20. The composition of claim 19, wherein the conventional depilation accelerator comprises a urea, a thiourea, a biguanide, or a combination thereof.
21. A method of retarding the growth of superfluous hair on a body comprising applying to a region of the body having superfluous hair the composition of claim 1.
22. A method of retarding the growth of superfluous hair on a body comprising applying to a region of the body having superfluous hair the composition of claim 2.

**COSMETIC COMPOSITIONS HAVING RETARDING ACTION ON THE
REGROWTH OF SUPERFLUOUS HAIR**

ABSTRACT

The present invention relates to cosmetic compositions having retarding action on the regrowth of superfluous hair, more particularly to cosmetic compositions containing lipophilic extracts of *Serenoa* (*Serenoa repens*) enriched in fatty acids and with a reduced content of sterols.

PENNIE & EDMONDS DOCKET NO. 7914-092-999

COPY**DECLARATION FOR NON-PROVISIONAL PATENT APPLICATION***

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below at 201 et seq. beneath my name.

I believe I am the original, first and sole inventor if only one name is listed at 201 below, or an original, first and joint inventor if plural names are listed at 201 et seq. below, of the subject matter which is claimed and for which a patent is sought on the invention entitled

COSMETIC COMPOSITIONS HAVING RETARDING ACTION ON THE REGROWTH OF SUPERFLUOUS HAIR

and for which a patent application:

☒ is identified as Pennie & Edmonds docket no. 7914-092-999

☒ is attached hereto and includes amendment(s) filed on (if applicable)

☐ was filed in the United States on as Application No. (for declaration not accompanying application)

with amendment(s) filed on (if applicable)

☐ was filed as PCT international Application No. on and was amended under PCT Article 19 on (if applicable)

I hereby state that I have reviewed and understand the contents of the above identified application, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

EARLIEST FOREIGN APPLICATION(S), IF ANY, FILED PRIOR TO THE FILING DATE OF THE APPLICATION			
APPLICATION NUMBER	COUNTRY	DATE OF FILING (day, month, year)	PRIORITY CLAIMED
MI2000A000628	Italy	24-March-2000	YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>
			YES <input type="checkbox"/> NO <input type="checkbox"/>
			YES <input type="checkbox"/> NO <input type="checkbox"/>

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below.

PROVISIONAL APPLICATION NUMBER	FILING DATE

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code §112, I acknowledge the duty to disclose information known to me which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

NON-PROVISIONAL APPLICATION SERIAL NO.	FILING DATE	STATUS		
		PATENTED	PENDING	ABANDONED
09/781,301	February 13, 2001		✓	

* for use only when the application is assigned to a company, partnership or other organization.

PENNIE & EDMON

DOCKET NO. 7914-090-999

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

2 0 1	FULL NAME OF INVENTOR	LAST NAME DI PIERRO	FIRST NAME Francesco	MIDDLE NAME	
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	SIGNATURE OF INVENTOR 204			DATE	
2 0 5	FULL NAME OF INVENTOR	LAST NAME	FIRST NAME	MIDDLE NAME	
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	POST OFFICE ADDRESS	STREET	CITY	STATE OR COUNTRY	ZIP CODE
	SIGNATURE OF INVENTOR 205			DATE	

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

COPY

Application of: F. DI PIERRO

Continuation-in-Part of Appl. No. 09/781,301 filed
February 13, 2001

Group Art Unit: 1651

Appl. No.: To be assigned

Filed: Concurrently Herewith

Examiner: M. FLOOD

For: COSMETIC COMPOSITIONS HAVING
RETARDING ACTION ON THE
REGROWTH OF SUPERFLUOUS HAIR

Attorney Docket No.: 7914-092

**INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. § 1.97 AND § 1.98****BOX PATENT APPLICATION**Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Pursuant to Applicant's duty of disclosure under 37 C.F.R. § 1.56 and § 1.97(h), enclosed are copies of (17) references for the Examiner's review and consideration. These references are listed on the enclosed Form PTO-1449. These references were cited during prosecution of application no. 09/781,301.

Applicant respectfully requests that the Examiner review these references and make them of record in the present application by completing and returning the enclosed Form PTO-1449. Should additional copies of any references be needed, Applicants will submit them upon request.

As this Information Disclosure Statement is being filed after the period specified in 37 C.F.R. § 1.97(b) and before the mailing date of a final office action or notice of allowance the fee for this submission pursuant to 37 C.F.R. § 1.97(c)(2) is believed to be \$240.00. Please charge this fee and any additional fees to Pennie & Edmonds Deposit Account No. 16-1150.

Respectfully submitted,

Date: May 25, 2002By: Paul E. Dietze
Thomas G. Rowan

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LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

ATTY DOCKET

7914-09

APPLICANT

F. DI PIERRO

FILING DATE

Concurrently Herewith

APPLICATION NO

To be assigned

GROUP

1651

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	6,113,926	9/2000	Soler et al.	424	401	
	AB	5,547,673	8/1996	Bombardelli	424	195.1	
	AC	5,043,323	8/1991	Bombardelli et al.	514	25	
	AD	4,963,527	10/1990	Bombardelli et al.	514	25	
	AE	4,631,064	12/1986	Juneja	8	161	
	AF	4,413,004	11/1983	Lietti et al.	424	283	
	AG	4,187,291	11/1980	Marissal	424	94	
	AH	4,103,025	7/1978	Mustich	424	305	
	AI	3,981,681	9/1976	De La Guardia	8	161	
	AJ						
	AK						
	AL						
	AM						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AN	WO 00/02570	1/2000	WIPO (PCT)				
	AO	WO 98/33472	8/1998	WIPO (PCT)				
	AP	WO 97/05887	6/1997	WIPO (PCT)				
	AQ	EP 0283713 A2	9/1988	EPO				
	AR	EP 0275224 A2	7/1988	EPO				
	AS	EP 0250953 A1	1/1988	EPO				
	AT	FR 2,791,255	9/2000	France				
	AU	FR 2,168,202	1/1972	France				

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	AV	
	AW	
	AX	

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.